DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 15, 2014

Reichert Inc.
% Mr. Thomas M. Heckmann
Quality Assurance/Regulatory Manager
3362 Walden Avenue
Depew, NY 14043

Re: K141954
Trade/Device Name: Xcel 455 Slit Lamp
Regulation Number: 21 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: September 12, 2014
Received: September 15, 2014

Dear Mr. Heckmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141954

Device Name
Xcel 455 Slit Lamp

Indications for Use *(Describe)*
The Xcel 455 Slit Lamp is an AC-powered slit lamp biomicroscope that is intended for use in examining the anterior eye segment, from the corneal epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma, which affect the structural properties of the anterior segment of the eye

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

**SUBMITTER**


**Submitter/Applicant Owner**

Reichert, Inc.
3362 Walden Avenue
Depew NY, 14043 USA
716-686-4500

**Contact Person**

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**Date Summary Prepared** July 3, 2014

**NAME OF DEVICE**

**Proprietary Name** Xcel 455 Slit Lamp
also known as: Xcel® 455 Slit Lamp, Xcel™ 455 Slit Lamp, Xcel® 455, Xcel™ 455, or Xcel 455.

**Common Name** Slit Lamp
**Regulation Number** 21 CFR Part 886.1850
**Classification Name** AC-powered slitlamp biomicroscope
**Regulatory Class** II
**Product Code** HJO

## PREDICATE DEVICE

**Marketed device claiming equivalence to**

Reichert claims the Xcel 455 slit lamp is substantially equivalent to the Reichert Xcel 255 Slit Lamp, 510(k) # K063750.

The proposed indications for use for the Xcel 455 are identical to the indications for use of the Reichert Xcel 255 Slit Lamp.

## DEVICE DESCRIPTION

The Xcel 455 slit lamp is a general purpose examination instrument used in a wide range of eye care practices. Slit lamps are used for ophthalmic observation of the structures of the eye. By controlling the light source, nature of slit, and filters, physicians, optometrists, ophthalmologists and eye care technicians can observe various structures in the eye. The Xcel 455 can be used on any patient; there are no contraindications.

Ophthalmic slit lamp design has not changed in decades, and like most, including the predicate Xcel 255, the Xcel 455 slit lamp consists of two fundamental subsystems, the illumination source to illuminate the eye to be examined, and the microscope to enable the practitioner to view the structures of the eye under magnification.

The Xcel 455 uses a low voltage (6 Volt, 20 Watt) dimmable halogen lamp, and a selection of 4 color filters, or none, to illuminate the eye. The device uses a stereo microscope with 5 selections of magnification ranges, from 6.5x to 40x, to view the structure. There is a mount that allows other devices to attach in line with the optical path, such as a prism type contact tonometer.

Like the predicate Xcel 255 device, the Xcel 455 device uses a steel body and glass lenses. The scientific principle of all slit lamps is to project light onto a patient's eye, so that a doctor may view the eye and its structures through a microscope.

## INDICATION FOR USE

The Xcel 455 Slit Lamp is an AC-powered slit lamp biomicroscope that is intended for use in examining the anterior eye segment, from the corneal epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma, which affect the structural properties of the anterior segment of the eye.

## TECHNOLOGICAL CHARACTERISTICS

The manufacturing process for the Xcel 455 slit lamp is the same as the process used for the predicate Xcel 255 slit lamp. The fundamental configuration difference of the Xcel 455 slit lamp is that the light source is above the optical path, and reflected into the path from above. In comparison, the Xcel 255 slit lamp has the optical light source below the optical path, and is reflected into the path from below. The devices use the same technology of universal power supply rheostat to control the same halogen light source, use manual adjustment

of filters, optical settings, and X-Y position. All controls are manual. Neither the Xcel 455 nor its predicate Xcel 255 have data collection, display systems, motors, or software.

**DETERMINATION OF SUBSTANTIAL EQUIVALENCE**

The determination of substantial equivalence was based upon nonclinical performance data. The determination of substantial equivalence did not include clinical data.

**BRIEF SUMMARY OF NONCLINICAL TESTS AND RESULTS**

The Xcel 455 was evaluated to IEC 60601-1:2007 (3rd edition) for electrical safety, and passed.
The Xcel 455 was evaluated to IEC 60601-1-2 for EMC compliance, and passed at Class A radiated emissions limits.
The Xcel 455 was evaluated to ISO 10993-1 for biocompatibility of the forehead & chinrest materials and passed.
The Xcel 455 was evaluated to ISO 15004-1 for environmental tolerance of ophthalmic devices and passed.
The Xcel 455 was evaluated to ISO 15004-2 for assessment of photo-biological safety of light intensity limits, and passed.
The Xcel 455 was evaluated to ISO 10939, which requires assessment to ISO 15004-1, 15004-2, and IEC 60601-1, and passed.

These results support determination of substantial equivalence because they show that the Xcel 455 slit lamp, is a safe device, and an effective device, built to the norms of the industry, just like its predicate.

**CONCLUSION**

Based upon the test results, and the comparison to the long established predicate Reichert Xcel 255 slit lamp which uses the same technology and indication for use, Reichert believes the Xcel 455 slit lamp is as safe and effective, and performs as well as or better than the predicate device with respect to its intended use.